



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request

Cancer Trials Support Unit (National Cancer Institute)

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Michael Montello, Pharm. D., Cancer Therapy Evaluation

Program (CTEP), 9609 Medical Center Drive, MSC 9742, Rockville, MD 20850 or call non-toll-free number 240-276-6080 or E-mail your request, including your address to: montellom@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Cancer Trials Support Unit (CTSU) (NCI), 0925-0624, EXTENSION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Cancer Therapy Evaluation Program (CTEP) establishes and supports programs to facilitate the participation of qualified investigators on CTEP-supported studies, and to institute programs that minimize redundancy among grant and contract holders, thereby reducing overall cost of maintaining a robust treatment trials program. Currently guided by the efforts of the

Clinical Trials Working Group (CTWG) and the Institute of Medicine (IOM) recommendations to revitalize the Cooperative Group program, CTEP has funded the Cancer Trials Support Unit (CTSU). The CTSU collects standardized forms to process site regulatory information, changes to membership, patient enrollment data, and routing information for case report forms. In addition, CTSU collects annual surveys of customer satisfaction for clinical site staff using the CTSU Help Desk, the CTSU web site, and the Protocol and Information Office (PIO). An ongoing user satisfaction survey is in place for the Oncology Patient Enrollment Network (OPEN). User satisfaction surveys are compiled as part of the project quality assurance activities and are used to direct improvements to processes and technology.

OMB approval for an extension to the existing approval is requested for one year.

There are no costs to respondents other than their time. The total estimated annualized burden hours are 25,204.

Estimated Annualized Burden Hours

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hour
CTSU IRB/Regulatory Approval Transmittal Form	Health Care Practitioner	9,000	12	2/60	3,600
CTSU IRB Certification Form	Health Care Practitioner	8,500	12	10/60	17,000
CTSU Acknowledgement Form	Health Care Practitioner	500	12	5/60	500
Withdrawal from Protocol Participation Form	Health Care Practitioner	50	12	5/60	50
Site Addition	Health Care Practitioner	25	12	5/60	25

CTSU Roster Update Form	Health Care Practitioner	50	12	4/60	40
CTSU Radiation Therapy Facilities Inventory Form	Health Care Practitioner	20	12	30/60	120
CTSU IBCSG Drug Accountability Form	Health Care Practitioner	11	12	10/60	22
CTSU IBCSG Transfer of Investigational Agent Form	Health Care Practitioner	3	12	20/60	12
Site Initiated Data Update Form	Health Care Practitioner	10	12	10/60	20
Data Clarification Form	Health Care Practitioner	341	12	20/60	1,364
RTOG 0834 CTSU Data Transmittal Form	Health Care Practitioner	60	12	10/60	120
MC0845(8233) CTSU Data Transmittal	Health Care Practitioner	50	12	10/60	100
CTSU Generic Data Transmittal Form	Health Care Practitioner	500	12	10/60	1,000
CTSU Patient Enrollment Transmittal Form	Health Care Practitioner	200	12	10/60	400
CTSU P2C Enrollment Transmittal Form	Health Care Practitioner	15	12	10/60	30
CTSU Transfer Form	Health Care Practitioner	20	12	10/60	40
CTSU System Account Request Form	Health Care Practitioner	20	12	20/60	80
CTSU Request for Clinical Brochure	Health Care Practitioner	75	12	10/60	150
CTSU Supply Request Form	Health Care Practitioner	75	12	10/60	150
CTSU Web Site Customer Satisfaction Survey	Health Care Practitioner	275	1	15/60	69
CTSU Helpdesk Customer Satisfaction Survey	Health Care Practitioner	325	1	15/60	81
CTSU OPEN Survey	Health Care Practitioner	60	1	15/60	15
PIO Customer Satisfaction Survey	Health Care Practitioner	100	1	5/60	8
Concept Clinical Trial Survey	Health Care Practitioner	500	1	5/60	42

Prospective Clinical Trial Survey	Health Care Practitioner	1000	1	5/60	83
Low Accrual Clinical Trial Survey	Health Care Practitioner	1000	1	5/60	83
ANNUALIZED TOTALS		22,785	237,560		25,204

Dated: November 10, 2016

Karla Bailey
Project Clearance Liaison
National Cancer Institute, National Institutes of Health
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